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Via Electronic Submission

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Re: Environmental Law Foundation Comments on Modifications to Proposed Amendments to Cal Code Regs., title 27, section 25821(a) and (c), Calculating Intake by the Average Consumer of a Product

Dear Ms. Vela:

Environmental Law Foundation (ELF) would like to thank OEHHA for the opportunity to submit comments to the July 2019 modifications to the proposed amendments to California Code of Regulations, title 27, section 25821, subdivisions (a) and (c)(2). ELF writes today to express disappointment with OEHHA's decision not to proceed with the amendment to subdivision (c)(2). (ELF continues to support the October 2018 changes to subdivision (a) and is not expressing an opinion here on the July 2019 edits to that provision.)

The October 2018 amendments to subdivision (c)(2) proposed requiring the use of the arithmetic mean to find the calculated average for the average consumer's rate of intake or exposure to a listed chemical in a consumer product. By choosing not to proceed with the amendments, OEHHA will allow manufacturers to continue to use the geometric mean to find the rate of intake or exposure. This will be an unfortunate consequence. Requiring the arithmetic mean would allow for clarity and consistency, ensure all inputs are weighed equally, and limit the use of the geometric mean to understate outlying inputs.

The status quo—allowing manufacturers to use the geometric mean—is a flawed state of affairs and OEHHA should require the use of the arithmetic mean. The use of the arithmetic mean would, in OEHHA's own words, "add clarity and consistency to the exposure calculation[s]" for both manufacturers and the courts. (OEHHA, Initial Statement of Reasons (ISOR), October 2018, p. 7.) Under current law, courts have allowed defendants to use the geometric mean to calculate the rate of exposure. (See

Environmental Law Foundation v. Beech-Nut Nutrition Corp. (2015) 235 Cal.App.4th 307, 316.) Unless all data points in a sample have the same value, the geometric mean will always produce a lower calculated average than one calculated using the arithmetic mean. (*Id*. at 325, fn.7.) The federal Environmental Protection Agency has found that "the arithmetic mean is appropriate regardless of the pattern of daily exposures over time" and that the "geometric mean . . . bears no logical connection to the cumulative intake that would result from long-term contact with site contaminants." (U.S. Environmental Protection Agency, Supplemental Guidance to RAGS: Calculating the Concentration Term (1992) Publication 9285.7-081, p. 3.) The EPA gave an example of a scenario where the geometric mean would be "much lower" than the arithmetic mean:

> Assume the daily exposure for a trespasser subject to random exposure at a site is 1.0, 0.10, 1.0, 0.01, 1.0, and 0.1 units/day over an 8-day period. Given these values, the cumulative exposure is simply their summation, or 4.04 units. Dividing this by 8 days of exposure results in an arithmetic mean of 0.505 units/day. This is the value we would want to use in a risk assessment for this individual, not the geometric mean of 0.1 units/day. Viewed another way, multiplication of the geometric mean by the number of days equals 0.8 units, considerably lower than the known cumulative exposure of 4.04 units.

(*Ibid.*) Although the EPA was not dealing with consumer product–based consumption in the above example, the underlying mathematical principles are relevant to circumstances such as the one that OEHHA's regulation attempts to clarify. The EPA example shows how the geometric mean can understate the larger data points in the overall total and decrease the number of individuals who are informed of potential exposures.

Of course, if OEHHA were to proceed with its originally proposed amendments to subdivision (c)(2), OEHHA would not be disallowing other methodologies if circumstances warrant. The regulation's language would still allow for the use of other methodologies when appropriate; in particular, the October 2018 amendments would not change the language at the beginning of subdivision (c) stating that the provided methods of calculating the level of exposure to a listed chemical are based on assumptions that may be overridden if "more specific and scientifically appropriate data are available."[1]

The purpose of Proposition 65 is to ensure that individuals are warned of

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[1] Moreover, section 25801, subdivision (a) of the regulations states that "[n]othing in this article shall preclude a person from using evidence, standards, assessment methodologies, principles, assumptions or levels not described in this article to establish that a level of exposure has no observable effect at one thousand (1,000) times the level in question."

exposures to the listed chemicals. OEHHA itself recognized this when it issued its Initial Statement of Reasons and found that all individual consumers should be weighed "equally for purposes of calculating intakes or exposures." (ISOR at p. 8.) "[T]he arithmetic mean takes into account the magnitudes of all measured values" and allows for all exposures to be recognized in the final calculated average. (ISOR at p. 7.) The arithmetic mean is not influenced only by high outliers, but rather weighs high and low outliers equally. By contrast, the geometric mean deemphasizes outliers in general, and "the more variable the measurements, the more the geometric mean underestimates the expected exposure." (ISOR at p. 8.) Manufacturers can misuse the geometric mean because it underestimates the outliers and results in a lower calculated average.

Requiring the use of the arithmetic mean is the best way to fulfill the policy behind Proposition 65. The statute's intent is in part to allow individuals to "be informed about exposures to chemicals that cause cancer, birth defects, or other reproductive harm." (Safe Drinking Water and Toxic Enforcement Act of 1986, Voter Information Guide, Gen. Elec. (Nov. 4, 1986), p. 53.) OEHHA has the authority to "adopt and modify regulations, standards, and permits as necessary . . . to further its purposes." (Health & Saf. Code § 25249.12, subd. (a).) OEHHA has a duty to inform consumers about exposures to listed chemicals and to prevent the misuse of methodologies by manufacturers which could limit the consumers who would be notified.

The use of the arithmetic mean may result in more consumers being warned of potential exposures, but this would, in fact, align with the public policy behind Proposition 65. Consumers should be adequately informed of exposures to the listed chemicals in order to make informed decisions when they purchase products. If OEHHA does not proceed with the proposed amendment to subdivision (c)(2), OEHHA is making a choice to continue to allow the use of the geometric mean, an action which would be counter to the public policy behind Proposition 65.

ELF urges OEHHA to proceed with the amendment to subdivision (c)(2) establishing the arithmetic mean as the default method of calculating the rate of intake for consumer exposures.

Sincerely,

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Environmental Law Foundation